

Implementation and Management of Model-based Drug Development

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Model-based Drug Development (MBDD) is evolving as a promising approach to improve decision-making in the drug development process. Pharmaceutical companies are increasingly embracing Sheiner's "Learn and Confirm" paradigm of knowledge building and use modeling and simulation as a key decision-making tool. M&S leaders from four companies (Bristol-Myers Squibb, Eli Lilly, Novartis, Pfizer) will present case studies that illustrate important concepts and challenges of the implementation and management of MBDD. Three key areas will be discussed: (1) mindset change (strategy), (2) process change (tactic), and (3) organization change (commitment). The following questions/challenges will be addressed: How are M&S scientists strategically integrated in the organization? How are M&S scientists successfully collaborating with clinicians and statisticians? How are M&S scientists noticeably adding value to the organization? What works well? What has not worked so well in the past? What can we learn from mistakes? What is our vision for 2010? 2020? This session will facilitate the application of Sheiner's "Learn and Confirm" paradigm not only to the drug development process but also to the implementation and management of Model-based Drug Development within the pharmaceutical industry.